

REMARKS

Claims 1-18 were pending in the present application and were rejected on various grounds. Claims 1 - 3, 5 - 7, 9 - 10, 12, and 17 - 18 are amended and claim 14 is cancelled without prejudice to more clearly claim the present invention and to expedite prosecution of the present application.

Claims 1 - 11 were rejected under 35 USC 112, second paragraph, in regard to the meaning of "axis" argued by the Examiner to be a *straight* line. Applicant amends claim 1, 5, 9, 17 and 18 with regard to the use of "axis" to expedite prosecution of the present application. Applicant believes that the rejection of claims 1 - 11 under 35 USC 112 is overcome.

Claims 1 - 10 and 12 - 18 were rejected under 35 USC 102(e) as being anticipated by Brown, ('199). The Examiner argues that Brown discloses an expandable hoop support and procedure for opening an artery substantially as claimed, composed of a material disposed about a first axis and about a second axis and having a coil memory, and a cylindrical delivery means to constrain the coil in a linear configuration being either a rod fit within the coil or a tube fit over the coil, and wherein the coil reconfigures into an original preformed configuration, that Brown's stent is adapted to hold open the vessel, inherently has a larger diameter than the vessel, and that it has openings that allow some blood into vessel openings or branch vessel.

Applicant notes that Brown's stated purpose, and what Brown teaches is "...to retain embiotic devices or materials, such as micro coils or embolic liquids, deployed within the aneurysm and prevent the embolic devices from migrating out of the aneurysm and into the patient's vasculature." and to "...block or divert at

least a portion of the blood flow away from the entrance of the aneurysm" (col 5, lines 2 - 9). Also, at Brown's aneurysm target sites, every device disclosed is smaller than the target site.

By contrast, the present invention according to claim 1, as amended, comprises:

- "a. a preformed hoop composed of material disposed to form a first coil which first coil is disposed to form a second coil having an outer diameter, having memory retaining properties, and having one of a rounded and a ball end; and
- b. cylindrical delivery means for constraining said second coil in to a linear configuration wherein said deliver means and said coil are adapted for insertion into said flexible tube at a target site unsupported aperture size and said delivery means is then removed, said hoop will then reconfigure to said second coil configuration wherein said double coil outer diameter is configured to be larger than said target site unsupported aperture size and configured to urge said target site aperture to said flexible tube nominal opening

not found in the cited art of record. Independent claim 9, as amended, provides similar patentably distinctive features, and the invention according to claim 5, as amended, includes:

- a. determining an artery structure nominal opening size;
- b. providing a preformed hoop composed of a primary coil of material having one of a rounded and a ball end said primary coil being wound to encircle a second axis to form a secondary coil having an outer diameter matching said nominal opening size, and instilling memory retaining properties into said preformed hoop to urge said material into said double coil;
- c. providing a cylindrical delivery means for constraining said secondary coil into a linear configuration;
- d. inserting said hoop and said delivery means into an artery at said target site having an unsupported aperture size less than said nominal opening size; and
- e. removing said delivery means whereby said hoop remains in said artery to support said artery in an open position wherein said secondary coil outer diameter is larger than said target site unsupported aperture size and said secondary coil is configured to urge said target site aperture to said nominal opening size.

Applicant argues that the Final status of the outstanding Office Action is premature in that the claimed feature, even prior to the present amendment, of "double coil outer diameter is configured to be larger than said target site unsupported aperture size" is not present in Brown. All embodiments and suggestions in Brown provide a placement at the target site less than the aneurysm size. Furthermore, the Examiner has not provided a previously requested reference basis for her assertion in the prior Office Action that Brown teaches or discloses a procedure for opening an artery so that the Applicant can completely respond, leaving the clear indication that there is no basis for such rejection. Thus a *prima facie* basis for the present rejection has not been established. Applicant respectfully requests a withdrawal of the Final status of the outstanding Office Action.

As previously argued, the cited art teaches the exact opposite of the presently claimed invention, wherein Brown retains devices or materials inwardly to restore by narrowing or occluding the target site vessel wall, from which the present invention, which operates against an occlusion to outwardly urge and expand the target site to assume the nominal vessel opening, is distinguished. The Examiner's assertion that Brown teaches or discloses a procedure for opening an artery is completely without support; so that the Applicant can completely respond, the Applicant respectfully requests the Examiner to provide explicit basis for her statement thereof.

Applicant further amends claims 1, 5 and 9 to include the further inventive feature of primary loops "having one of a rounded and a ball end" not found in the cited art of record. Claim 5 is amended to include the features of claim 14, now cancelled without

prejudice, wherein the feature of "determining an artery structure nominal opening size" and "providing a preformed hoop...wound...to form a secondary coil having an outer diameter matching said nominal opening size" not addressed in the present Office Action, not found in and believed to be patentably distinguishable over Brown. Thus, the present invention of Claims 1, 5, and 9 is patentably distinguishable from all of Brown's teachings and embodiments. The claims dependent on independent claims 1, 5, and 9, provide additional inventive features which further patentably distinguish the present invention over the cited art of record. Applicant therefore believes that the rejection of claims 1 - 10 and 12 - 18 under 35 USC 102(e) as being anticipated by Brown, ('199) is overcome.

Claims 1, 3-5, 7 - 15 and 17 - 18 were rejected under 35 USC 102(e) as being anticipated by Farzin-Nia ('076), wherein the Examiner argues that Farzia-Nia discloses a expandable hoop support and procedure for opening an artery substantially as claimed. The Examiner states that Farzia-Nia discloses a preformed hoop stent (col 3, lines 47-50; col. 2, line 4) composed of a coil 10 of material comprising twisted multi-filar strands 12 forming strand 10 wound to form coil 14, and has memory, a cylindrical deliver means to constrain coil into a linear configuration, and wherein when delivery means is removed the coil reconfigures into an original preformed configuration, and is adapted to hold open the vessel (col 3, lines 47-50), an open or irregular spacing of the secondary coil (Fig. 3), such spacings adapted for placement near an opening in the vessel.

Applicant again argues that the Final status of the present Official Action is premature in that the Examiner's asserted teaching of a stent in the reference is not present in the

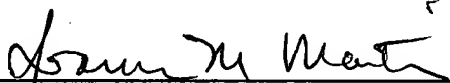
reference, leaving only a mere suggestion that the disclosed stranded wire could be used in a stent of undisclosed structure or method. Moreover, the Farzia-Nia element 10 said to be a 'coil' is actually a single wire comprising twisted strands, structurally distinct from a 'coil' as clearly understood by one of ordinary skill in the art and according to the present application. Furthermore, Farzia-Nia is completely silent as to any procedure for opening an artery, as claimed or otherwise. Thus, the Examiner fails to provide a *prima facie* basis for the present rejection as stated. Applicant again respectfully requests that the Final status of the outstanding Office Action be withdrawn.

Regarding the substance of the rejection over Farzia-Nia which teaches only strands 12 which are twisted or braided (e.g. Col 2, line 35 and elsewhere) to form a stranded wire 10 making coil springs 14. Farzia-Nia simply discloses only a single coil, not the primary and secondary coils as claimed. The Examiner is apparently stating that a twisted wire is a coil, which is believed not supported by any reference or knowledge in the art. As this goes to an inventive aspect and not merely 'filling in the blanks', Applicant respectfully requests that the Examiner provide a reference that supports her position that a twisted wire is a coil per se, as provided by MPEP 2144.03, so that Applicant may respond thereto. Furthermore, Farzia-Nia is completely silent as to any procedure for opening an artery, as claimed or otherwise, teaching only structures referencing orthodontics (e.g. Fig. 3). The Examiner's assertion is clearly without support. Therefore, Farzin-Nia fails to provide each and every element of the present inventive structure, or even a suggestion thereof, and thus the Examiner has failed to provide a basis on which to base the

rejection. Applicant therefore believes that the rejection of claims 1, 3 - 5, 7 - 11, and 17 - 18 under 35 USC 102(e) as being anticipated by Farzin-Nia ('076) is improper and should be withdrawn, and in the alternative, is overcome.

Applicant, having amended the Claims, and having distinguished the present invention over the cited art of record, believes that the present application is in condition for allowance. Applicant respectfully requests reconsideration and allowance of the present application. A copy of the previously submitted Revocation of Power and Appointment of New Power of Attorney is enclosed and correction of mail address to that listed thereon is requested. The Examiner is invited to call the Applicant's undersigned attorney should she feel that such a call would further the prosecution of the present application.

Respectfully submitted,
R. Edward Winters


By Joanne M. Martin, Reg. No. 29,328
40 North Spring Street
Concord, NH 03301-3902
603 228 1611 Email: JMM@venue1.com
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